VIII. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

ARTHREX CORKSCREW FT, K061665

JUL 25 2006

MANUFACTURER / SPONSOR

Arthrex, Inc.
1370 Creekside Boulevard
Naples, Florida 34108-1945

510(K) CONTACT:

Ann Waterhouse, RAC
Regulatory Affairs Project Manager
Telephone: (239) 643-5553 ext. 1179
FAX: (239) 598-5539

TRADE NAME:

Corkscrew FT

COMMON NAME:

Screw, Fixation, Bone

PRODUCT CODE /

CLASSIFICATION NAME

HWC/ 21 CFR 888.3040

Screw, Fixation, Bone

GAT/ 21 CFR 878.5000

Suture, Nonabsorbable Synthetic Polyethylene

PREDICATE DEVICE:

Arthrex Bio-Corkscrew FT, 5.5 mm: K043337

DEVICE DESCRIPTION AND INTENDED USE:

The Arthrex Corkscrew FT with a suture eyelet molded or internally fixed and a fully threaded body, are 4.5 mm to 6.5 mm in diameter and are offered on a driver.

The Arthrex Corkscrew FT suture anchor is intended for fixation of suture to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and pelvis in, but not limited to, the following procedures:

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair.

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, and Iliotibial Band Tenodesis.

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction.

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

Pelvis: Bladder Neck Suspension for female urinary incontinence due to urethral hypermobility of intrinsic sphincter deficiency.

SUBSTANTIAL EQUIVALENCE SUMMARY

The Arthrex Corkscrew FT, 4.5 mm and 6.5 mm are substantially equivalent to the predicate Arthrex Bio-Corkscrew FT, 5.5 mm in which the basic features and intended uses are the same. Any differences between the Arthrex 4.5mm and 6.5 mm Corkscrew FT and the 5.5 mm Bio-Corkscrew FT predicate are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the Corkscrew FT ranging in size from 4.5 mm to 6.5 mm, in both PEEK and PLLA, is substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2006

Arthrex, Inc.
% Ms. Ann Waterhouse, RAC
Regulatory Affairs Project Manager
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K061665
Trade/Device Name: Arthrex Corkscrew FT
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MAI
Dated: June 27, 2006
Received: July 17, 2006

Dear Ms. Waterhouse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

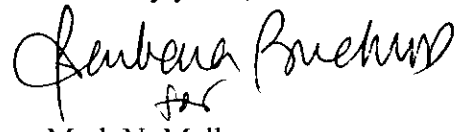
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or 240-276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

III. Indications for Use Form

510(k) Number (if known): K061665

Device Name: Arthrex Corkscrew FT

Indications for Use:

The Arthrex Corkscrew FT Suture Anchor is intended for fixation of suture to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and pelvis in, but not limited to, the following procedures:

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair.

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, and Iliotibial Band Tenodesis.

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction.

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

Pelvis: Bladder Neck Suspension for female urinary incontinence due to urethral hypermobility of intrinsic sphincter deficiency.

Prescription Use X AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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